FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF COMMUNICATION TESTING FOR DRUG PRODUCTS (0910-0695)

TITLE OF INFORMATION COLLECTION: Physician Interviews on FDA-Approved Labeling

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   FDA-approved labeling, or prescribing information, is an FDA-approved summary of the information needed to use a prescription drug safely and effectively. The labeling is written for healthcare practitioners. There are two types: Physician Labeling Rule (PLR) format (newer labeling format) and "non-PLR" format labeling (older labeling format). FDA's Drug Labeling Coordinating Committee identified several topics related to the newer labeling format that would benefit from input from physicians. These topics include the resources physicians use to find information about prescription drugs; physicians' interpretation of specific language in labeling; and presenting information on risks, drug interactions, and overdosage in labeling. The purpose of this information collection is to conduct qualitative research focusing on physicians' use of, preferences for, and understanding of FDA-approved labeling.

2. **Intended use of information:**

   In line with the purpose of the generic clearance, FDA will use this information to learn about its communications for drug products. This research is intended to inform FDA's thinking on FDA-approved labeling and serve as a basis for potential future quantitative research on this topic. Findings from this qualitative research will not be used to make policy or regulatory decisions.

3. **Description of respondents:**

   The study will consist of 70 individual in-depth remote interviews with practicing physicians across the United States via telephone and computer. General inclusion/exclusion requirements built into the screening protocol will ensure that all participants are practicing physicians who write at least 50 prescriptions per week and have not participated in a research interview and/or focus group within the last three months. We will exclude physicians who have ever worked for the Department of Health and Human Services, a market research firm, a pharmaceutical company, or RTI. Participants must consent to having their interview audio-recorded and livestreamed.

   Two different types of physicians will be interviewed for this study. Approximately half will be primary care physicians and approximately half will be specialists. The gender, race/ethnicity, and ages of the participating physicians will be self-identified by participants during the screening process. The goal is for the participating physicians to be generally reflective of the demographic composition of physicians in the U.S. according to the American Medical Association (AMA).

4. **Date(s) to be conducted and location(s):**

We plan to conduct the interviews between December 2019 and January 2020.

Physicians will be recruited to participate in this study from across the United States, with interviews taking place remotely via telephone and computer.

5. **How the Information is being collected:**

Recruitment Procedures

FDA's contractor, RTI International, will work with L&E Research to recruit practicing primary care physicians and specialists for a 60-minute one-on-one remote interview (via phone and computer). Participants will be recruited through L&E Research's healthcare professional panel. The healthcare professional panel consists of thousands of physicians, nurse practitioners, physician assistants, nurses, and other healthcare professionals nationwide. When joining the panel healthcare providers complete a short screener with information about themselves (medical degree, type of practice, demographics, etc.) and agree to receive invitations to participate in studies. L&E Research will use this proprietary panel to identify primary care physicians and specialists based on the panelists' profile information to invite for further screening. While not anticipated, if L&E Research has difficulty recruiting the number and type of participants needed, they may investigate the possibility of working with AYTM Market Research, one of their partner panels. Recruitment and screening will be conducted by telephone or via an online survey. Recruitment will be conducted using the following methods:

> Telephone: A recruiter from L&E Research will call potential participants to invite them to participate in the study. If the potential participant is interested, the recruiter will then complete the screening process by telephone.
>
> Email: L&E Research will send potential participants an email explaining the study and inviting them to complete a brief screener linked to the email. The brief screener will include a subset of the approved screening questions. Potential participants that are interested in participating and appear to qualify will be contacted by phone to complete the screening process.

The recruitment phone script and emails are included in **Appendix A.** The study screener is included in **Appendix B.** L&E Research will schedule eligible physicians who are interested in participating for the interview during predetermined time slots based on availability. After being scheduled, participants will receive a confirmation email from L&E Research that includes the date and time of the interview and instructions for using the Zoom platform (see **Appendix C).** A second email with the consent form will be sent asking participants to indicate their willingness to participate or not by checking a box (see **Appendix D)**.

Method

During the recruitment process, participants will be given instructions for connecting to the interview using Zoom. Once connected, the participant and interviewer will be able to see each other and a whiteboard that can be used to show drug labels and other study materials for participants to read as the interviewer reads them aloud. Having the information in written format may be helpful as a reference as the interviewer asks the questions.

FDA and other project staff will be able to observe interviews in listen-only mode. The use of video allows us to establish strong rapport with participants, observe nonverbal expressions, present sample materials on screen, and ensure that participants are fully engaged in the sessions (i.e., not multitasking). The participants will be notified of both the audio recording and livestreaming during the screening process, in the consent form, as well as before the interview starts.

Three experienced RTI team members trained in qualitative research will conduct the interviews. During each session, one interviewer will lead the discussion from his or her computer and a separate note-taker and logistics coordinator will assist. Interviewers will use the interview discussion guide to guide the interview (see **Appendix E**). The interviewer and participant will both be visible on screen and we will encourage participants to use a phone line (rather than computer microphone) for their audio connection. FDA team members will be able to observe from any Internet-connected computer or device; however, they will not be visible on the video platform. The logistics coordinator will be available to address any issues such as difficulty logging into the platform.

We will audio-record all sessions and will produce verbatim transcripts in Adobe PDF format based on these recordings. The transcripts will not contain identifying information, and all other files containing names (except for the informed consent forms and audio files) will be destroyed following the completion of the interviews. Consent forms and audio files will be destroyed after 5 years.

6. **Confidentiality of Respondents:**

We will implement several procedures to protect participants' confidentiality, including the following:

a. In addition to recording answers to screening questions, the L&E Research will collect names, email addresses, and telephone numbers for eligible individuals who are willing and available to participate in an interview. L&E Research will use this contact information to send individuals the consent form, instructions for joining the online interview, and remind them of their upcoming appointment and to return their signed consent form if they have not already done so. This PII will be recorded separately from the screener and stored in the firm's secure proprietary internal software system only at L&E Research and will be destroyed after all the interviews have been conducted. RTI will have access to contact information in case a participant does not show up for the interview and needs to be called. RTI will destroy all contact information immediately following completion of the interviews. Only L&E Research and RTI will have access to

participant names and contact information; FDA will have access only to de-identified screening data.

b. The informed consent form covers aspects related to confidentiality. At the beginning of each interview, the interviewer will remind participants of this information. The consent forms will also contain language that notifies participants of both the audio recording and livestreaming of the interview. While the interview will be audio-recorded, the video component will not be recorded and will be limited to livestreaming only. Before each interview begins, the interviewer will confirm consent by receiving verbal affirmation from the participant to audio record and to livestream the session. Due to the importance of complete data, in the event that verbal consent for the audio recording and livestreaming is not given, the participant will be thanked for their time and the interview will be terminated.

c. If a participant discloses PII during the interview, this information will be redacted from the transcripts before delivery to FDA. FDA will not receive the audio-recordings of the interview.

d. Only FDA and RTI staff authorized by the FDA project officer and RTI project director will be provided with instructions for observing the interviews by video and telephone. Additionally, to help prevent unauthorized people from overhearing the discussion, participants will be reminded to make sure they participate where others cannot overhear the conversation. Livestreaming connections will be secure, using industry-standard firewalls and security practices. All data will be encrypted in transit using secure hypertext transfer protocol (HTTPS). All equipment will be operated and maintained according to industry-standard practices, and all software will be validated using industry-standard, quality-assurance practices.

e. There will be no link between the data collected and participants' identities. FDA will not have the full names or any contact information for any of the participants.

f. All screener and interview data will be analyzed and reported in aggregate.

g. At both FDA and RTI, access to project data and materials will be limited to only research staff working on the project who have been granted access by the FDA project officer or RTI project director.

h. All study files will be stored on password-protected computers at both FDA and RTI and destroyed within 5 years of the study's end date.

These confidentiality methods will be approved by RTI's IRB and FDA's IRB before collecting any information. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

7. **Amount and justification for any proposed incentive:**

Upon completing their interview, participants will receive a token of appreciation by check from L&E Research: $200 for primary care physicians and $300 for specialists. Based on the contractor's experience, and recent consultation with recruiting firms, these incentives are close to current market rates and should help ensure high participation and show rates. Although market incentive rates for physicians are higher than those being offered here, we hope the flexibility the remote interview methodology affords—e.g., no travel time to/from facility, conducted on the physicians' schedules—will offset the lower incentive amount.

As participants often have competing demands for their time, incentives are used to encourage participation in research. When applied in a reasonable manner, incentives are not an unjust inducement and are an approach that acknowledges respondents for their participation.[1] The use of incentives treats participants justly and with respect by recognizing and acknowledging the effort they expend to participate. In this particular research, we are asking physicians to provide thought-intensive, open-ended feedback on concepts that require a high level of engagement.

Incentives must be high enough to equalize the burden placed on respondents with respect to their time and cost of participation,[2] as well as provide enough motivation for them to participate in the study rather than another activity. Particularly in the case of primary care physicians and specialists, incentives need to be high enough that these physicians make time in their busy schedules and participate in the study.

If the incentive is not adequate, participants may agree to participate and then not show up or drop out early. Low participation may result in inadequate data collection or, in the worst cases, loss of government funds associated with moderator and observer time.[3] Additionally, low participation can cause a difficult and lengthy recruitment process that in turn, can cause delays in launching the research, both of which lead to increased costs.

8. **Questions of a Sensitive Nature:**

None.

9. **Description of Statistical Methods (i.e. Sample Size & Method of Selection):**

No statistical methods will be used.

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1 Halpen, S.D., Karlawish, J.H., Casarett, D., Berlin, J.A., & Asch, D.A. (2004). Empirical assessment of whether moderate payments are undue or unjust inducements for participation in clinical trials. *Archives of Internal Medicine, 164*(*7*), 801-803.

2 Russell, M.L., Moralejo, D.G., & Burgess, E.D. (2000). Participants' perspectives. *Journal of Medical Ethics, 26*(*2*), 126-130.

3 Morgan, D.L. & Scannell, A.U. (1998). *Planning focus groups*. Thousand Oaks, CA: Sage.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Table 1 shows the estimated annual reporting burden.

	No. of Respondents	**No. of Responses per Respondent**	**Total Annual Responses**	**Average Burden per Response (in Hours)**	**Total Hours**
Number to complete the screener	330	1	330	.0833 (5 min.)	27.5
Number to complete the study	70	1	70	1.00 (60 min.)	70
Total			372		97.5

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